AIPPI Biotechnology Standing Committee Study Question - Patentability of microbiomes

Questions

I. Current law and practice

Please answer all questions in Part I on the basis of your Group's current law. For each question that follows, please answer YES or NO AND provide a brief explanation.

1) Are there any specific laws or regulations in your country that address and/or regulate the patenting of Microbiome Inventions? [YES/NO] If so, please summarize the current state of the law and patent office practice in your jurisdiction concerning the patenting of Microbiome Inventions.

NO - There are no specific laws or regulations specifically regulating the patenting of microbiome inventions.

However, Section 1 of the Finnish Patents Act recognizes that inventions which concern a microbiological or other technical process or a product obtained by means of such a process are patentable. An invention may be patentable even if it concerns a product consisting of or containing biological material or a process by means of which biological material is produced, or if the subject of the invention is a biological material which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature. These provisions are based on Articles 2 and 3 of the EU Directive 98/44.

“Microbiological process” means any process involving or performed upon or resulting in microbiological material (Section 1(5) of the Patents Act). “Biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Section 1(6) of the Patents Act). These encompass, e.g., bacteria, yeasts, molds, cell cultures, and viruses, as well as DNA and RNA molecules containing genetic information. (Finnish Patent and Registration Office’s Patent Handbook)

According to the Finnish Patent and Registration Office, biological material may be the subject of an invention if it is produced by a technical process, such as isolation or purification, and if it has an industrial application. The mere observation of (previously unknown) biological material occurring in nature is considered a discovery that is not eligible for patent protection. If the invention involves biological material originating from a specific person, or if such material is used in the invention, the use or patenting of the material requires the informed and voluntary consent of the person from whom the material originated. (Finnish Patent and Registration Office’s Patent Handbook)

We are not aware of any case law or established patent office practice relating to patentability of microbiome inventions. The Finnish Patent and Registration Office generally follows the practice of the European Patent Office.

2) Does your jurisdiction exclude strains of isolated microorganisms and/or microbiomes from patentability? [YES/NO] You may add a brief explanation.

NO

Section 1 of the Patent Act explicitly provides for the patentability of isolated biological material.

3) Does your jurisdiction exclude man-made microbial consortia comprising isolated naturally occurring microorganism(s) from patentability? [YES/NO] You may add a brief explanation.

NO

Section 1 of the Patent Act explicitly states that a product consisting of or containing biological material can be patented and that biological material which is produced by means of a technical process, even if it previously occurred in nature, can be subject matter of a patent.

4) Does your jurisdiction exclude man-made compositions comprising isolated naturally occurring microorganism(s) from patentability? [YES/NO] You may add a brief explanation.

NO

Section 1 of the Patent Act explicitly states that a product consisting of or containing biological material can be patented and that biological material which is produced by means of a technical process, even if it previously occurred in nature, can be subject matter of a patent.

5) If you have answered yes to any of questions 2 to 4 above, please provide a brief explanation of the basis for the exclusion from patentability. In particular, please identify whether the exclusion is based on the issue of lack of eligible subject matter (e.g., such as the 101 provisions in the US) and/or based on lack of substantive patentability requirements (i.e. novelty, lack of inventive step obviousness and/or insufficiency of disclosure/enablement).

N/A. As answered above, Finnish law does not exclude isolated microorganisms, microbial consortia, or compositions comprising isolated microorganisms from patentability.

6) Does your jurisdiction allow for the patenting of Microbiome Inventions derived from the human microbiome? [YES/NO] If so, please explain under what conditions this is allowed.

YES

The Finnish Patent Act does not categorically exclude Microbiome Inventions derived from the human microbiome. As such, the patentability of Microbiome Inventions requires for the standard conditions of patentability to be met (i.e., novelty, inventive step, industrial application, sufficient disclosure). However, certain limitations are set.

According to Section 1(a) of the Finnish Patent Act, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. However, according to the

following subsection, such elements may be patented, if the element in question is isolated from the human body and general conditions for patentability are met, even if the structure of the element is identical to its natural form.

Further, according to Section 1(b) of the Finnish Patent Act, patents shall not be granted for inventions the commercial exploitation of which would be contrary to public order or morality. Processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes are in particular considered contrary to public order or morality.

7) Are there any enablement/written disclosure/sufficiency requirements particularly pertaining to or relevant for Microbiome Inventions in your jurisdiction which must be satisfied? [YES/NO] You may add a brief explanation. For example:

a. Is a deposit necessary? [YES/NO] You may add a brief explanation.

YES

According to Sections 8(1) and 8a of the Patent Act, if the invention concerns or requires the use of biological material that is not generally available and cannot be described in a reproducible manner in the description, such biological material must be deposited in order to ensure the reproducibility of the invention. The deposit must be made no later than the date of filing the application, or, if priority is sought in respect of the biological material, no later than the priority date of the application. (Finnish Patent and Registration Office's Patent Handbook). In practice, no deposits are made if it is possible to otherwise sufficiently describe the Microbiome Invention, for example by naming the species involved.

b. If a deposit is necessary, does this deposit need to be under the Budapest Treaty? [YES/NO/NOT APPLICABLE] You may add a brief explanation.

YES

According to the Section 17a of the Patent Decree (669/1980, as amended), biological material must be deposited with a depositary institution in accordance with the Budapest Treaty, or with another depositary institution approved by the EPO in the manner required by the Budapest Treaty.

c. Is reference to a genetic marker necessary? [YES/NO/NOT APPLICABLE]
You may add a brief explanation.

NO - There is no general requirement that reference to a genetic marker would be necessary.

According to the Section 11 of the Patent Order (PRH/1217/01/2022), if the application contains: a nucleotide sequence comprising at least ten consecutive, precisely defined nucleotides, or an amino

acid sequence comprising at least four consecutive, precisely defined amino acids, the application must include a sequence listing prepared in accordance with WIPO Standard ST.26.

d. Is definition via structural features necessary, such as 16s RNA?
[YES/NO/NOT APPLICABLE] You may add a brief explanation.

NO - There is no general requirement that specific structural features should be defined.

8) Does your jurisdiction allow for the patenting of uses of and/or methods using Microbiome Inventions? [YES/NO] You may add a brief explanation.

YES. Section 1 of the Finnish Patents Act explicitly mentions that the patentability of inventions relating to microbiological processes or other technical processes, or to products obtained by such processes is not restricted. For the purposes of the Finnish Patents Act, a microbiological process means a process that uses microbiological material, relates to microbiological material, or produces microbiological material

a. If YES, please explain under what conditions the patenting of uses of
and/or methods using Microbiome Inventions is allowed.

YES
The general conditions for patentability apply.

b. If YES, is there any difference between claims directed to medical vs.
non-medical (e.g. cosmetic) applications?

YES
Therapeutic, diagnostic or surgical methods, practiced on humans or animals, are not patentable but medical purpose-bound product claims are accepted. Non-medical applications are not covered by the prohibition and can be patented on the same conditions as any other invention.

9) What are the key issues or challenges that arise when enforcing patent rights related to Microbiome Inventions in your jurisdiction?

We are not aware of any Finnish case law on the enforcement of patent rights related to microbiome inventions. Enforcement of patent rights related to microbiome inventions may include for example the following challenges:

- Monitoring and detection: The patent holder must monitor that their patent is not infringed. However, microbiome-based products and their use may be difficult to detect in practice, making it challenging for patent holders to identify potential infringers and to verify whether infringement is at hand or not. This may require complex laboratory experiments.

- Sufficiency of disclosure: Given the complexity and variability of microbiomes, ensuring adequate description and enablement may be particularly challenging for microbiome inventions.

- Invalidity challenges: The natural occurrence of microbiomes in various environments may present challenges in establishing novelty. Validity challenges based on newly discovered prior art or natural occurrence may also arise due to the evolving nature of microbiome science

- Scope of protection issues: The patent protection for biological material extends to any biological material obtained from the patented material through propagation or multiplication in identical or differentiated form, which possesses the same properties. However, determining whether accused microbiome compositions possess "the same properties" as patented microbiomes may be technically complex and fact-intensive.

II. Policy considerations and proposals for improvements of your Group's current law

10) According to the opinion of your Group, is your current law regarding the patenting of Microbiome Inventions adequate and/or sufficient? [YES/NO] You may add a brief explanation.

YES
We consider that the current law regarding the patenting of microbiome inventions is adequate, but more case law and guidance on the application of current laws would be welcome.

11) Are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question? [YES/NO] You may add a brief explanation.

YES
Patent offices could be more active in sharing best practices regarding the sufficient disclosure of microbiome inventions.

III. Proposals for harmonisation

12) Is there a need for international harmonization of patenting policies for Microbiome Inventions? [YES/NO] You may add a brief explanation.

YES. Harmonization would (i) provide greater legal certainty for inventors, patentees as well as investors and researchers working on Microbiome Inventions, (ii) ensure consistent protection across jurisdictions (iii) support innovation and development in this emerging field and (iv) facilitate technology transfer and international collaboration.

13) Should isolated naturally occurring microorganisms, isolated naturally occurring microbiomes, and/or microbial consortia comprising isolated naturally occurring microorganisms be excluded from patentability?

a. Naturally occurring microorganisms should be excluded from patentability [YES/NO] You may add a brief explanation.

NO. If there is an industrial application for an isolated naturally occurring microorganism, it should be considered a patentable invention.

b. Isolated naturally occurring microbiomes should be excluded from patentability [YES/NO] You may add a brief explanation.

NO. If there is an industrial application for an isolated naturally occurring microbiome, it should be considered a patentable invention.

c. Microbial consortia comprising isolated naturally occurring microorganisms should be excluded from patentability [YES/NO] You may add a brief explanation.

NO. If there is an industrial application for microbial consortia comprising isolated naturally occurring microorganisms, it should be considered a patentable invention.

14) Should there be specific requirements for patent applications related to Microbiome Inventions (e.g., defining microorganisms and/or microbial consortia in the Microbiome Invention)? [YES/NO] You may add a brief explanation.

NO
As a starting point, microbiome inventions should be subject to the same requirements as other inventions. Deposit should be offered as an option for inventions that cannot be sufficiently disclosed by other means. Broad function-based definitions should be discouraged and attention should be paid to the clarity of the scope of protection.

15) Are there any additional issues concerning any aspect of patenting Microbiome Inventions that you consider relevant to harmonization considerations? [YES/NO] You may add a brief explanation.

NO.

16) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.

NA